

PUBLIC HEALTH REPORT

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Safe Medical Devices

MEDICAL DEVICES ARE an important part of every physician's diagnostic and therapeutic equipment, from the stethoscope, sphygmomanometer and clinical thermometer to the pressure transducer and heart-lung machine.

The State Department of Public Health, Bureau of Food and Drug, has the responsibility of assuring the safety and efficacy of all devices intended for use in the diagnosis, cure or treatment of disease, or intended to affect any structure or function of the human body. In California they must be manufactured on licensed premises, and good manufacturing practices must prevail in such establishments. Labeling should indicate whether the device is intended for investigational use only or may be used for treatment and, if so, whether medical supervision is required. Directions, description of hazards, and warnings must be provided unless they are commonly known. For a new device which is not generally recognized among qualified experts as safe and effective for use, clearance must be obtained before it may be sold.

The Department is currently interested in learning of any defective or improperly constructed medical devices so that hazards to patient and

doctor and allied medical personnel may be eliminated. Deaths have been reported to us recently from explosions of dental gas installations; also instances of improperly controlling heating units in incubators; electrical shocks from physiotherapy equipment; improperly insulated dialysis equipment; dialysis membranes with a high rupture rate; ventilators which vary with voltage changes and spontaneously fail; and pacemakers with short life expectancies.

The Department is currently licensing California device manufacturers whose manufacturing facilities are adequate and whose products are made under good manufacturing practices. We suggest that physicians and hospitals inquire whether their California-manufactured devices come from sources licensed by this Department and that we be notified of any unlicensed manufacturers of medical devices in this state that may come to your attention. We are also interested in learning of any instance of medical equipment failure or inadequate performance since problems with medical devices involve not only their condition at time of sale or installation, but also the effects of time and continued use. We urge every institution with medical equipment to implement a preventive maintenance and inspection program to make sure that equipment in current use is performing safely and effectively at all times, and that fail-safe mechanisms or back-up equipment are readily available in the event of component or instrument failure. A competent medical equipment safety engineer can provide invaluable services in protecting the health of patients.